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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

MSDI-303/PC379.04

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on September 11, 2008

Signature

Typed or printed name

Brad A. Schepers

Application Number

09/869,813

Filed

January 3, 2002

First Named Inventor

Lawrence M Boyd

Art Unit

3733

Examiner

David C Comstock

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒

attorney or agent of record.

Registration number 45,431☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

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Sept. 11, 2008

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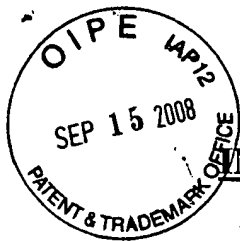
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re patent application of:	)	Before the Examiner
Lawrence M. Boyd et al.	)	David C. Comstock
	)	
Application Serial No. 09/869,813	)	Group Art Unit 3733
	)	
Filed January 3, 2002	)	Ref. No. MSDI-303/
	)	PC379.04
INTERVERTEBRAL SPACERS WITH SIDE	)	
WALL ACCESSIBLE INTERIOR CAVITY	)	September 11, 2008

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the final Office Action dated May 13, 2008 and the Advisory Action dated August 18, 2008, please consider the following. A Notice of Appeal and form PTO/SB/33 Pre-Appeal Brief Request for Review are submitted herewith along with the requisite appeal fee under 37 CFR 41.20(b)(1). Additionally, a fee in the amount of \$120 is submitted herewith for a one-month extension of time. Please provide any additional extensions of time necessary and charge any additional fees which may be due to Deposit Account No. 12-2424, but not to include the payment of issue fees.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

September 11, 2008

Date of Deposit

Brad A. Schepers

Name of Registered Representative

Signature

September 11, 2008

Date of Signature

## **REMARKS**

Claims 1, 2, 6-10, 13-15, 17, 18, 20, 52, 54, 56, 59, 61-64, 66-68, 75 and 83-95 were pending for the final Office Action dated May 13, 2008. Reconsideration of the final Office Action was requested by the Applicant via a response filed on July 14, 2008 in which the pending independent claims 1, 13 and 52 were not amended, but which presented detailed arguments in support of patentability. Additionally, dependent claims 83 and 91 were rewritten in independent form, dependent claim 64 was amended to more clearly recite the claimed invention, and new dependent claims 93, 94 and 95 were added which depend indirectly from independent claims 1, 13 and 52, respectively. An Advisory Action mailed on August 18, 2008 contends that the claim amendments "raise new issues that require further consideration and/or search", and asserts that "[t]he issues raised in all pending claims have been addressed during prosecution, notwithstanding any typographical oversight. Examiner's position regarding the explicit disclosure of Michelson (5,593,409) as well as the obviousness of determining an 'appropriate shape, size or form' of the openings (as recognized by Michelson and supported by case law) have been set forth in the record." Entry of Applicant's response was refused.

As an initial matter, the Applicant respectfully disagrees with the decision to refuse entry of Applicant's response to the final Office Action. The Applicant notes that no amendments were incorporated into independent claims 1, 13 and 52 and rewritten independent claims 82 and 91, which constitute all of the independent claims. Since none of the independent claims 1, 13, 52, 82 and 91 were amended, the Applicant submits that the outstanding response does not raise new issues that require further consideration and/or searching. Accordingly, the Applicant requests consideration of the response to the final Office Action and entry of the same.

### **Non-Examined Claims 83-92**

In reply to a non-final Office Action dated October 9, 2007, the Applicant filed a response on January 8, 2008 in which independent claims 1, 13 and 52 and dependent claims 9, 59 and 62 were amended, and new dependent claims 83-92 were added, with newly added claims 83-92 depending either directly or indirectly from independent claims 1, 13 and 52. A final Office Action dated May 13, 2008 rejected claims 1, 2, 6-10, 13-15, 17, 18, 20, 52, 54, 56, 59, 61-64, 66-68 and 75. However, the final Office Action did not address or assert any rejections directed to newly added claims 83-92 which were added to the subject application in Applicant's response filed on January 8, 2008. Indeed, the Office Action Summary does not even

acknowledge that claims 83-92 are pending, and the brief grounds of rejection set forth on pages 2 and 3 of the Office Action do not in any way address the subject matter recited in claims 83-92. For example, the final Office Action does not set forth any rational or reasoning as to how U.S. Patent No. 5,593,409 to Michelson (the only asserted reference) discloses or in any way suggests an implant having first and second end walls that are “fixed and non-removable” relative to an elongated implant body, or which are “formed integral with the side wall”.

The Applicant notes that MPEP §706.02(j) states that “[t]o support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” (Citations omitted; emphasis added). Additionally, MPEP §2142 states that “[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness”, and that “[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that ‘rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” (Citations omitted; emphasis added).

As indicated above, the subject matter recited in claims 83-92, including the subject matter recited in rewritten independent claims 83 and 91, was not addressed in the outstanding Office Action and does not appear to have been examined. The Applicant submits that the outstanding Office Action does not present “a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious”, and does not present a “clear articulation of the reason(s) why the claimed invention would have been obvious”, nor is there any “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. As a result, a *prima facie* case of obviousness has not been established with regard to claims 83-92. Accordingly, the Applicant requests issuance of a Notice of Allowance, or alternatively that finality of the outstanding Office Action be removed followed by reopening of prosecution and issuance of a non-final Office Action which addresses the patentability of each of the pending claims, including non-examined claims 83-92.

### **Patentability of the Claims**

Claims 1, 2, 6-10, 13-15, 17, 18, 20, 52, 54, 56, 59, 61-64, 66-68 and 75 stand rejected as being unpatentable over the '409 patent to Michelson. The final Office Action indicates that Michelson does not disclose "that the opening in the side wall discontinuity could extend over at least about 50% of the length and at least 20% of the circumference" of the implant body. Nevertheless, the final Office Action asserts that it would have been obvious to provide an opening having such features "since Michelson explicitly discloses that the opening(s) may have 'ANY shape, size or form'." (See pages 2-3). The Applicant notes that the rejection of independent claims 1, 13 and 52 is based solely on the general allegation that "the openings 128 may have any . . . size". Although Michelson states that the openings 128 may have "any shape, size or form", such statement is non-specific and very general in nature. The bone ingrowth openings 128 are much smaller than those called for in independent claims 1, 13 and 52, and although the size of the openings 128 may be increased to some extent, one of ordinary skill in the art would not be led by the Michelson disclosure to increase the size of one such bone ingrowth opening 128 "to extend over at least about 20% of the outer circumference of said body and along at least about 50% of the length of said body" based solely on the general statement that "the openings 128 may have any . . . size". Indeed, the purpose of the openings 128 is to allow for bone ingrowth into the internal chamber 114 (see col. 10, ll. 8-12), and Michelson does not disclose the use or configuration of these openings 128 to "allow for loading osteogenic material into said interior chamber", as recited in independent claims 1, 13 and 52. Instead, the Michelson disclosure discusses the provision of a large opening extending through the end of the implant to allow for loading of bone growth material into the hollow interior of the implant.

Moreover, independent claims 1, 13 and 52 also recite "a plurality of secondary bone ingrowth openings extending through said outer circumferential surface" and communicating with the interior chamber. These secondary bone ingrowth openings are configured to allow for bone ingrowth into the interior chamber of the implant and are specifically recited as being "sized smaller than said side wall opening", with the side wall opening defined by the side wall discontinuity. The Applicant notes that Michelson does not disclose these features. Referring to Figures 23, 31, 36 and 42, even assuming arguendo that any of the small openings extending through the flat wall portions could be construed as "a side wall opening" defined by a side wall discontinuity, the openings 428, 528, 628 and 829 extending through the circumferential surface

of the arcuate wall portions are not “sized smaller than said side wall opening”. To the contrary, the openings defined by the arcuate wall portions (which have been construed as implant portions defining an outer circumferential surface) are sized larger than the openings extending through the flat wall portions (which have been construed as a side wall discontinuity).

Once more, although Michelson discloses that “the openings 128 may have any shape, size or form”, there is no indication that the openings 428, 528, 628 and 829 extending through the arcuate wall portions are “sized smaller than” the openings extending through the flat side walls. Furthermore, the Applicant notes that the Office Action does not set forth any bases or rational as to how Michelson discloses or suggests “a plurality of secondary bone ingrowth openings extending through said outer circumferential surface” that are “sized smaller than said side wall opening” defined by the side wall discontinuity. Additionally, independent claim 52 recites that the generally cylindrical body has “external threads”. Once again, the Office Action does not set forth any bases or rational as to how Michelson discloses these features. Indeed, Michelson discloses that the implant is provided with ratchetings so that the implant “may be pushed into the cylindrical disc space D by direct linear advancement since it requires no thread to pull it forward through the spine.” (See col. 9, ll.16-19). For at least these reasons, a *prima facie* case of obviousness has not been established with regard to independent claims 1, 13 and 52. Additionally, independent claims 83 and 91 recite each of the elements and features of independent claims 1 and 52, respectively, and further recite that “said end walls are fixed and non-removable relative to said elongated body”, features which are neither disclosed nor suggested by Michelson. (See Applicant’s response filed on July 14, 2008). Accordingly, the Applicant submits that independent claims 1, 13, 52, 83 and 91 are patentable over Michelson.

Based on the forgoing, the Applicant requests further review and consideration of the subject application and allowance of the same.

Respectfully submitted,

By: 

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